

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ROGER CARLTON,)	
)	
Plaintiff,)	
)	
v.)	Case No. 22-2478
)	
STRYKER CORPORATION,)	
and STRYKER SOFIA MS, LLC.)	
)	
)	
Defendants.)	

COMPLAINT FOR DAMAGES AND REQUEST FOR JURY TRIAL

Comes now the Plaintiff, Roger Carlton, by counsel, and for his claim against Defendants, Stryker Corporation and Stryker Sofia MS, LLC, alleges and states as follows:

I. PARTIES

1. At all times relevant herein, Roger Carlton was a citizen of Fountaintown, Indiana.
2. At all times relevant herein, Thermedx, LLC (“Thermedx”) was a manufacturer of medical devices, which designed, manufactured, marketed, distributed and sold the Fluid Management System automated pressure irrigation infuser (“Thermedx infuser”) throughout the United States, including throughout the State of Indiana.
3. At all times relevant herein, Defendant Stryker Corporation (“Stryker”) was a manufacturer of medical devices and apparatuses and was a corporation organized and existing under the laws of Michigan and regularly conducted business in, received economic benefit from, and had sufficient minimum contacts with the State of Indiana.
4. At all times relevant herein, Stryker Sofia MS, LLC (“Stryker Sofia”) was a manufacturer of medical devices and apparatuses and was a corporation organized and existing under the laws of Michigan and regularly conducted business in, received economic benefit from,

and had sufficient minimum contacts with the State of Indiana.

5. Upon information and belief, in 2021 Thermedx, Stryker, and Stryker Sofia were involved in a business transaction that resulted in the sale, purchase, acquisition and/or merger of the three corporate entities. Plaintiff is unaware of the precise nature of the business transaction and which entities remain following the business transaction. Plaintiff has sued Thermedx in a case pending in this Court in a case styled *Roger Carlton v. Thermedx, LLC*, Case No. 1:22-cv-1707-JRS-MG (“Original Lawsuit”) and has sought leave to amend his complaint in that case to add Stryker and Stryker Sofia as defendants, but as of the filing of this Complaint, the Court has not ruled on that motion and because of the approaching expiration of the statute of limitations, Plaintiff files this action against Stryker and Stryker Sofia. (*See* Dkt. 19 in Original Lawsuit.)

6. Additionally, in a lawsuit filed on October 4, 2022, Plaintiff Hanover Insurance Company has sued Thermedx and Plaintiff Roger Carlton seeking a judicial determination that Hanover Insurance has no duty to defend or indemnify Thermedx in the Original Lawsuit, arguing that Thermedx did not disclose Carlton’s claim when it applied for a Hanover Insurance Company insurance policy. *Hanover Insurance Company v. Thermedx, LLC and Roger Carlton*, Case No. 1:22-cv-1957-TWP-MJD (dkt. 1).

7. Given the business transaction that occurred in 2021 and Hanover Insurance’s declaratory judgment suit, Plaintiff sues Stryker and Stryker Sofia as one or both of these entities may have agreed to acquire or assume the liabilities of Thermedx as part of the business transaction, including the claims made by Roger Carlton herein.

8. Therefore, Stryker and Stryker Sofia are proper defendants to this suit as one or both may be legally responsible to pay for any judgment entered against Thermedx in the Original Lawsuit.

II. JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over the present action as there exists complete diversity among the parties and the amount in controversy exceeds \$75,000.00, exclusive of interest and cost in accordance with 28 U.S.C.A §1332. Plaintiff is a citizen of the State of Indiana and Defendants Stryker and Stryker Sofia are citizens of the State of Michigan

10. Venue is proper in the United States District Court, Southern District of Indiana, Indianapolis Division, because a substantial part of the events or omissions giving rise to the claim occurred in Indianapolis, Indiana pursuant to 28 U.S.C. §1391.

III. FACTS

11. On December 29, 2020, Plaintiff Roger Carlton was a patient of Dr. Kevin Rice, a urologist, at Indiana University Health University Hospital in Indianapolis, and was being treated for a bladder tumor. On that date, on the recommendation of Dr. Rice, Mr. Carlton underwent a procedure known as a transurethral resection of a bladder tumor, known as a TURBT procedure.

12. On that date, Mr. Carlton was placed under general anesthesia for the TURBT procedure, which is performed with a resectoscope which permitted the surgeon to visualize the interior of the bladder to assess and resect the bladder tumor. In order to perform the procedure, Dr. Rice utilized the Thermedx infuser model P2000, serial/lot number 20170075 for the purpose of filling the bladder with warm saline to irrigate and distend the bladder to facilitate the TURBT procedure. The saline is introduced to the bladder through the resectoscope under pressure generated by the Thermedx infuser.

13. During the TURBT procedure performed by Dr. Rice, upon information and belief, the Thermedx infuser malfunctioned and the pressure generated by the product to fill Mr. Carlton's bladder surged from 62 mmHG to more than 500 mmHG, well above the safe pressure level for the introduction of fluid into an organ of the human body. The surge in pressure caused Mr.

Carlton's bladder to explode and the saline solution to spray out of the tubing utilized for the procedure and out the back of the infuser.

14. As a direct and proximate result of the dangerously defective Thermedx infuser, Mr. Carlton suffered severe injuries including the removal of his bladder and prostate, incurred medical expenses, and pain and suffering and will continue to incur medical expenses and experience pain and suffering into the future.

**COUNT I –
INDIANA PRODUCT LIABILITY ACT**

15. Plaintiff incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

16. At all times relevant herein, Thermedx was in the business of designing, manufacturing, marketing and selling the Thermedx infusers to hospitals and other medical facilities such as IU Health.

17. As entities which are now potentially legally responsible for the acts and omissions of Thermedx as the designer, manufacturer, and seller of the Thermedx infuser, Defendants are liable to Plaintiff for his injuries and damages under Indiana law as:

- (a) Plaintiff was harmed by the defective condition of the Thermedx infuser which caused and allowed a surge in pressure which damaged Mr. Carlton's bladder and prostate causing them both to being removed ("defective condition");
- (b) The defective condition existed at the time it was distributed or sold by Thermedx;
- (c) As a patient undergoing a urological procedure for which the Thermedx infuser was specifically designed, constructed and marketed, it was foreseeable to Defendants that Mr. Carlton's physician would utilize the Thermedx procedure during Mr. Carlton's TURBT procedure;
- (d) Thermedx was in the business of selling the Thermedx infuser; and

- (e) The Thermedx infuser reached IU Health in the condition it was sold.

18. As designed and manufactured, upon information and belief, the Thermedx infuser was in a defective condition because at the time it was sold or otherwise distributed by the Thermedx, it was in a condition (a) not contemplated by reasonable persons among those considered expected users or consumers of the Thermedx infuser; and (b) that was unreasonably dangerous to the expected user or consumer when used in reasonably expectable way.

20. As labeled, the Thermedx infuser was defective because Thermedx failed to properly package the Thermedx infuser to give reasonable warnings of danger about the product and Thermedx failed to give reasonably complete instructions on the proper use of the Thermedx infuser when the Thermedx, by exercising diligence, could have made such warnings or instructions.

21. Defendants are strictly liable to Plaintiff for any manufacturing defect which permitted the Thermedx product to be distributed or sold in the defective condition.

22. Thermedx failed to exercise reasonable care under the circumstances in designing the Thermedx infuser which permitted the Thermedx infuser to be distributed or sold in the defective condition and are liable for Plaintiff's resulting injuries and damages under Indiana law.

23. Thermedx failed to exercise reasonable care under the circumstances in providing the warning or instructions for the Thermedx infuser which permitted the Thermedx infuser to be distributed or sold in a defective condition and are liable for Plaintiff's resulting injuries and damages under Indiana law.

24. As a direct and proximate result of the defective condition of the Thermedx infuser, Plaintiff sustained traumatic and catastrophic damages for which Defendants are liable under Indiana law.

25. As Defendant Stryker and/or Defendant Stryker Sofia may have agreed to acquire or assume the liabilities of Thermedx, they may be liable for the defective condition of the Thermedx infuser that caused Plaintiff's damages.

WHEREFORE, Plaintiff, Roger Carlton, by counsel, prays for judgment against the Defendants, Stryker Corporation, and Stryker Sofia MS, LLC in an amount sufficient to compensate him for his injuries and damages, plus the cost of this action, and for all other relief just and proper in the premises.

JURY DEMAND

Comes now the Plaintiff, Roger Carlton, by counsel, and hereby requests trial by jury in this matter.

Respectfully submitted,

STEPHENSON RIFE, LLP

/s/ Brady J. Rife

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